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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,828	01/24/2002	Carlos Plata-Salaman	ORT-1573	3409

7590 12/19/2002

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EXAMINER
FISHER, LATONIA M

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,828	PLATA-SALAMAN ET AL.	
	Examin r	Art Unit	
	La Tonia M. Fisher	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-24 are pending in the application.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 provides for the use of fructopyranose sulfamate and erythropoietin in the preparation of medicament for treating neurodegenerative disorders, and Claim 24 provides for the use of topiramate and erythropoietin in the preparation of medicament for treating neurodegenerative disorders but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23 and 24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank et al. (WO 00/61138 A1) in view of Sachdeo (Topiramate: Clinical Profile in Epilepsy, Clin Pharmacokinet, May1998, 34(5):335-346) and in further view of Brines et al. (WO 00-66164).

Claims 1 is drawn to methods for treating neurological dysfunctions comprising co-therapy with a fructopyranose sulfamate and erythopoietin. Claim 2 limits Claim 1 in that the fructopyranose sulfamate is topiramate. Claim 3 is drawn to specific amounts of the fructopyranose sulfamate to be used in the method of Claim 1. Claim 4 limits Claim 1 wherein the erythropoietin is epoetin alfa. Claim 5 is drawn to specific amounts of the erythropoietin to be used in the method of Claim1. Claims 6 – 18 delimit the neurological dysfunctions of Claim 1 to specific, known neurological disorders. Claims 20 and 21 are drawn to compositions

comprising topiramate, erythropoietin and a pharmaceutically acceptable carrier. Claim 22 is drawn to a method for making a pharmaceutical composition comprising topiramate, erythropoietin and a pharmaceutically acceptable carrier.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Shank et al. teaches a method for treating chronic neurodegenerative disorders comprising administering a sulfamate carbohydrate or carbocyclic compound. See WO 00/61138 A1, Claim 1. The dosage amounts in Shank et al. for the compounds of Formula I in Claims 1 and 2 to be used in the method overlap substantially with Applicant's asserted ranges for therapeutic concentrations. See WO 00/61138 A1, p. 9, (Claims 3 and 4).

Shank et al. suggests the combination of multiple active agents to treat neurological disorders, WO 00/61138 A1 p. 7, lines 4-8 following Figure 3; however Sachdeo teaches combining topiramate, a known fructopyranose sulfamate, which adequately bridges the nexus between the invention as claimed and the prior art cited supra. See Sachdeo, p. 2, lines 8-9

Sachdeo teaches the use of topiramate as adjunctive therapy, combination therapy, for treating epilepsy, a known neurological dysfunction. See Sachdeo, p.2, lines 8-9. The dosage amounts in Sachdeo for the compounds of Formula I in Claims 1 and 2 to be used in the method

overlap substantially with Applicant's asserted ranges for therapeutic concentrations. See Sachdeo, p. 340, Col. 2, lines 22-26.

Brines et al. discloses compositions and methods for modulations and protection of excitable tissue, including neuronal tissue of the central and peripheral nervous system, and for enhancement of cognitive function by administering erythropoietin, erythropoeitin derivatives and/or recombinant erythropoietin. WO 00/61164, p. 9, lines 24 –6. Epoetin alfa is known in the art as a recombinant form of erythropoeitin. Several of the neurological disorders taught by Brines et al. to be treated by erythropoietin and derivatives of erythropoietin include in injuries resulting from seizure disorder, multiple sclerosis, stroke, disorders relating to the central nervous system and/or peripheral nervous system including age-related loss of cognitive function and senile dementia, chronic seizure disorders, Alzheimer's disease, Parkinson's, AIDS (acquired immunodeficiency syndrome) dementia, cerebral palsy, dementia, memory loss, amyotrophic lateral sclerosis, alcoholism, mood disorder, anxiety disorder, attention deficit disorder, autism, Wilson's disease, Creutzfeld-Jakob disease, Huntington's disease, brain or spinal cord trauma, heart-lung bypass, glaucoma, retinal ischemia or retinal trauma, post-surgical cognitive dysfunction, neuropsychiatric disorders, bipolar effective disorders, seizure disorders such as epilepsy and chronic seizure disorder. The dosage amounts in Brines et al. for the erythropoietin and derivatives of erythropoietin to be used in the method overlap substantially with Applicant's asserted ranges for therapeutic concentrations. See WO 00/61164, p. 23, lines 28-30. The examiner directs Applicant's attention to WO 00/61164, p. 23, lines 1-9 where Brines et al. teaches the precise dosage should be decided depending upon the condition and the immune status of the individual patient, according to standard clinical techniques.

Brines et al. also teaches pharmaceutical compositions which comprise erythropoeitin and/or erythropoeitin derivatives and a pharmaceutically acceptable carrier. WO 00/61164, p. 24, lines 7-8.

It would have been obvious for a person of ordinary skill in the art at the time the invention was made to combine a fructopyranose sulfamate and erythropoietin, including topiramate and epoetin alfa, into a single composition and administer such composition for treating neurological disorders, as Applicant has done with the above cited references before it. It requires little more than routine skill in the art to combine art recognized active agents and administer the combined composition to treat neurological disorders and related symptoms and conditions since the art discloses the these agents are individually used to treat neurological disorders and since Sachedo provides the suggestion to administer multiple agents for treating neurological dysfunction.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to La Tonia M. Fisher whose telephone number is (703) 306-5819. The examiner can normally be reached on Monday - Friday from 9:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (703) 308-4532. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

LMF
December 16, 2002

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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